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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,213	02/13/2002	Dominique Begon	F15026 US-CNT	9260

5487 7590 07/22/2004

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/075,213

Applicant(s)

BEGON ET AL.

Examiner

Lakshmi S Channavajjala

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 19-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 19-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Receipt of amendment and remarks dated 2-5-04 is acknowledged. Claims 11-18 have been canceled and new claims 19-30 have been added. Claims 1-10 and 19-30 are pending.

The following rejections from the previous action have been maintained:

1. Claims 1-7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,314,506 to Midler, Jr. et al.

Instant claims 19, 29 and 30 recite particles of sizes between 1 and 10. Midler teaches that the crystals are have a diameter equal to less than 20 microns (see claim 5 of Midler). Therefore for the reasons presented in the previous rejection and above teachings of Midler, new claims 19-25, 27 and 29-30 are also rejected under this section.

2. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Midler, Jr. in view of US 4,599,294 to Matsumoto et al.

New claim 26 is rejected under this section for the same reasons mentioned in the previous action and the above teachings of regarding particle sizes.

3. Claims 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,314,506 to Midler, Jr. et al in view of US 3,897,779 to Hansen.

New claim 28 is rejected under this section for the same reasons mentioned in the previous action and the above teachings of regarding particle sizes.

*Response to Arguments*

Applicant's arguments filed 2-5-04 have been fully considered but they are not persuasive.

MIDLER: Applicants argue that significant differences exist between the teachings of Midler ('506 patent) and the instant invention because instant invention clearly teaches that the ratio of the volume flow of anti-solvent to volume flow of medicament solution exceeds 2:1 and that an excess of anti-solvent is needed. Applicants argue that Midler teaches that the flow rate from each jet is 1.1 liter/min, or equal flow rate of anti-solvent and feed solution or even more feed solution than anti-solvent. Applicants also argue that while Midler teaches a ratio of greater than one (claims 16 of Midler), that ratio is hardly equal to the claimed ratio of 2:1. Applicants argue that Midler teaches wide ratios of feed solution to anti-solvent. However, the teachings of Midler are in the same field of endeavor and directed to solving the same problem as that of the instant i.e., producing particles of drugs or medicaments having high bioavailability and short dissolution times by avoid milling and introducing jet processes. As also agreed by applicants, Midler recognizes the volume flow of feed and anti-solvent as an important factor in producing crystals having desired particle size. As also admitted by applicants, Midler does suggest wide ratios of the volume flows and therefore, absent any criticality of the instant claimed velocity, it would have been within the scope of a skilled artisan to optimize the volume flows of the solvent and anti-solvents, and their ratios from the prior art teachings of wide ratios so as to achieve the desired particle sizes because Midler does suggest using higher velocities

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Applicants argue that Midler also significantly differs from instant invention in controlling the velocity of the jet streams to remove substantially cyclic variations resulting in higher quality of crystal. In support of the argument, applicants cite the data on page 10 of the instant specification to demonstrate that controlling the velocity of streams to remove cyclic variations. However, the data presented only includes velocities of 30 m/s or higher and do not include the lower velocities of prior art (taught by Midler). Accordingly, a meaningful comparison cannot be made between the flow rates (within and outside the claimed scope) and the cyclic variations and the quality of crystals. Further, instant claim does not clearly recite the means for controlling the variations. Thus, the limitation "velocity of each step is controlled" does distinguish from the method taught by Midler.

MIDLER IN VIEW OF MOTSUMOTO: Applicants argue that claim 8 is dependent upon claim 1 includes all the limitations of claim 1 and for the reasons argued claim 1 is not clearly obvious over Midler. Therefore, applicants argue that regardless of the solvent used, claim 8 is not obvious over the cited art. Applicants' arguments regarding Midler are not found persuasive for the reasons presented above. Applicants argue that Motsumoto is non-analogous art and therefore cannot be combined with Midler. However, the teachings of Motsumoto are directed to producing particles and dimethylformamide is recognized as one of the solvents. Further, instant claims do not specify a particular medicament or drug type and thus is broad. Therefore, it is examiner's position that the combination of Midler and Motsumoto is proper for the reasons presented in the last office action.

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MIDLER IN VIEW OF HANSEN: applicants argue that claim 10 dependent upon claim 1 includes all the limitations of claim 1 and for the reasons argued claim 1 is not clearly obvious over Midler. Applicants argue that Hansen teaches a method of treating asthma, and is based on the discovery that discharge from an aerosol container having therein a suspension of triaminiclonide acetate in a propellant can be suspended in a dry vaporized propellant mixed with air by the use of a deceleration chamber. Applicants argue that Hansen teaches nothing with respect to crystallizing the drug and hence claim 10 is unobvious. Applicants' arguments are not persuasive because Hansen teaches the claimed drug as having high surface area and small particles, which is also desired by Midler so as to achieve improved stability and purity. The argument that Hansen teaches the drug asthma is moot because instant claim does not specifically limit the use of the drug produced by the claimed process. Both Hansen and Midler are directed drug formulations having small particles of drug and are thus analogous in nature. Accordingly, the combination of references is proper and one of an ordinary skill in the art would have included triaminiclonide of Hansen in the method of producing drug particles of Midler with an expectation to produce small particles that have high bioavailability, which is also desired by Hansen.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

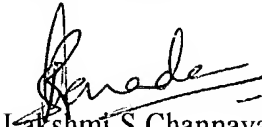
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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
July 19, 2004

  
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